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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,160	08/21/2000	Bent Hojgaard	06063.0019	7752

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FINNEGAN, HENDERSON, FARABOW, GARRETT &  
DUNNER LLP  
1300 I STREET, NW  
WASHINGTON, DC 20005

EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/642,160

Applicant(s)

HOJGAARD ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 38-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of request for extension of time (granted) and amendment both 12-12-01 is acknowledged. Claims 1-37 have been canceled and new claims 38-73 have been added.

#### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Denmark on 8-20-99. It is noted, however, that applicant has not filed a certified copy of the 1999 01145 application as required by 35 U.S.C. 119(b).

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 38-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valducci (EP 0 820 703; hereafter '703).

'703 teaches oral prolonged-release vitamin C/ rapid-release vitamin E formulations. The amount of vitamin C is within the instant ranges and the amount of vitamin E is about 30 mg (Example 10). Since the compositions of '703 appear to be the same as those of the instant claims, they would have the same plasma profile, absent a demonstration otherwise. If shown otherwise, it is the position of the examiner

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that adjustment of the dose of either vitamin would be within the ken of one skilled in the art for example to provide greater doses of vitamins in the instance where greater doses are needed such as in someone who is malnourished. The process limitations of claims 54-56 are not afforded any patentable weight as they are intended uses of the compositions.

### ***Response to Arguments***

3. Applicant's arguments filed 12-12-01 have been fully considered but they are not persuasive. Applicants argue that the amounts of vitamins in '703 are greater than the instant ranges, referring to example 9, and that while motivation to increase the amounts is provide, no motivation to decrease the amounts is provided. However, the assertion that only example 9 is directed to a combined vitamin C/E formulation is incorrect. Example 10 also gives an example of a prolonged vitamin C/ rapid-release vitamin E formulation. The amount of vitamin C is about 140 mg and the amount of vitamin E is about 30 mg. Thus, the amount of vitamin C is within the instant ranges and the amount of vitamin E is slightly lower. However, it is submitted that it would have been obvious to one skilled in the art at the time of the invention to increase the amount of vitamin E in the formulation. Applicants also argue that '703 does not teach the instant plasma levels or the ratio of vitamins. However, no data providing evidence thereto nor criticality thereof has been provided.

4. Claims 57-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valducci (EP 0 820 703; hereafter '703) in view of Sato et al (1993) or Valducci (EP 0 820 703; hereafter '703) in view of Niki (1986).

'703 is relied upon for all that it teaches as stated previously. '703 does not teach the instant methods of using the compositions for treatment of oxidative stress disorders.

Sato et al teaches that vitamin <sup>E</sup>~~A~~ and vitamin C interact synergistically to decrease oxidation of neurons in conditions of oxidative stress.

Niki teaches that vitamin <sup>E</sup>~~A~~ and vitamin C interact synergistically to decrease oxygen toxicity and subsequent occurrence of heart disease, rheumatoid arthritis, inflammatory disorders, cancer, and aging.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to use the compositions of '703 to treat oxidative stress with the motivation of maintaining high concentrations of vitamins C and E as vitamin C is otherwise rapidly eliminated by an organism to treat oxygen toxicity of neurons or peroxidation of biological molecules and tissues.

### ***Response to Arguments***

5. Applicant's arguments filed 12-12-01 have been fully considered but they are not persuasive. Applicants reiterate arguments that '703 is insufficient to obviate the instant limitations and that neither Sato nor Niki suggest modification to overcome the deficiencies of '703. However, previous statement in paragraph 3 *supra* are again pertinent. Example 10 of '703 also provides an example of the instant combined formulation of vitamin C and vitamin E.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
February 22, 2002

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600